REMARKS

Status of the Claims

Claims 1-12, 15-17 and 21 are pending in the present application. Claims 13, 14 and 18-20 have been cancelled without prejudice or disclaimer of the subject matter contained therein. Claim 21 is supported by claim 17.

Elections/Restrictions

Claim 1 has been amended consistent with the elected invention.

Rejection of Claims 11-20 under 35 U.S.C. 112, First Paragraph

Claims 11-20 are rejected by the Examiner under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Based on the Examiner's comments on page 3 of the Office Action, it appears that the Examiner is rejecting the method of use claims because they encompass "prevention" of disease. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

Contrary to the position taken by the Examiner, claims 11-20 are not all directed to method of use claims. Claims 11-15 are clearly directed to a composition. There is no requirement in the statute (e.g. 35 USC 112) that a composition is enabling for all uses. Therefore, the Examiner has failed to establish a prima facie case of non-enablement with respect to composition claims 11-15.

Further, this rejection is moot with respect to claims 18-20 since these claims have been cancelled. These claims have been cancelled because they are non-statutory type claims under U.S. practice. The

intended uses are encompassed by method claims 16 and 17.

Claims 16 and 17 have been amended to address the matters raised by the Examiner. Specifically, the term "preventing" has been deleted from these claims. Thus, the rejection is moot in view of the amendments to claims 16 and 17.

With respect to any issue regarding the sufficiency of disclosure of the inhibitors of acetylcholin esterease, the Examiner's attention is directed to the attached article entitled "Cholinesterase Inhibitors of Alzheimer's Disease", John C. Morris et al., Drugs 2001, 61(1): 41-52.

Alzheimer's disease (AD) is the most common age-related neurodegenerative disease and has become an urgent public health problem in most areas of the world. Substantial progress has been made in understanding the basic neurobiology of AD and, as a result, new drugs for its treatment have become available. Cholinesterase inhibitors (ChEIs), which increase the availability of acetylcholine in central synapses, have become the main approach to symptomatic treatment. ChEIs that have been approved or submitted to the US Food and Drug Administration (FDA) include tacrine, donepezil, metrifonate, rivastigmine and galantamine. In this review, the pharmacology and clinical experience to date is discussed together with their use and their potential benefits or disadvantages. ChEIs have a significant, although modest, effect on the cognitive status of patients with AD. In addition to their effect on cognition, ChEIs have a positive effect on mood and behavior. Uncertainty remains about the duration of the benefit because few studies of these compounds beyond one year have

been published. Although ChELs are generally well tolerated, all patients should be followed closely for possible adverse effects. There is no substantial difference in the effectivenes of the various ChEIs, however, they may have different safety profiles. The benefits of their use outweigh the risks and costs and, therefore, ChEIs should be considered as primary therapy for patients with mild to moderate AD.

As to papers showing the clinical efficacy of donepezil usefulness, the following two papers are attached:

a) Rogers SL et. al., A 24-week, double-blind, placebo-controlled trial of donepezil in patients with Alzheimer's disease: Donepezil Study Group. Neurology 1998; 50:136-45.

b) Rogers SL et. al., Donepezil improves cognition and global function in Alzheimer disease-a 15-week, double-blind, placebo-controlled study. Donepezil Study Group. Arch. Intern. Med. 1998; 158:1021-31.

Both were published before the application of the present invention.

Donepezil, referred to in the literature, is a compound having the same mechanism of action as the compound of the present invention. It is an inhibitor of acetylcholinesterase and is a commercially available medicament for treating Alzheimer's Disease with very strong sales in the world. Thus, one of ordinary skilled in the art will take it for granted that the compound(s) claimed in the present application are efficacious for senile dementia and cerebrovascular dementia.

Accordingly, the rejection in paragraph 3 of the Office Action should be withdrawn by the Examiner.

Rejection of Claims 1-20 under 35 U.S.C. 112, Second Paragraph

Claims 1-20 are rejected by the Examiner under 35 U.S.C. 112, second paragraph, for the reasons set forth in paragraph 4 of the Office Action. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The following paragraphs correspond to the headings in paragraph 4 of the Office Action:

(a) Claim 1 is said to be vague and indefinite in that it is not known what is meant by the period at the end of the fourth line. In response, Applicants have removed the period at the end of the fourth line of claim 1. This is clearly a non-narrowing amendment.

(b) Claim 1 is said to be vague and indefinite in that it is not known what is meant by the capital letter at the beginning of the fifth line. In response, Applicants have removed the capital letter at the beginning of the fifth line of claim 1. This is clearly a non-narrowing amendment.

(c) The Examiner rejects the language "R^5 and m have the same meanings as defined above" in claim 2. In response, Applicants have copied the definition of these terms from claim 1 and incorporated the definition of these terms into claim 2. This is clearly a non-narrowing claim amendment.

(d) The Examiner rejects the language "A, R^6 and q have the same meanings as defined above" in claim 6. In response, Applicants have

copied the definition of these terms from claim 1 and incorporated the definition of these terms into claim 6. This is clearly a non-narrowing claim amendment.

(e) Claims 11-14 are said to be vague and indefinite because it is not clear to the Examiner whether the claims are drawn to a compound, composition or even a complex composition. In response, the term "medicament" has been cancelled and the phrase "composition" has been substituted therefore. This is clearly a non-narrowing claim amendment.

(f) Claims 13 and 14 are cancelled since they are duplicative. The Examiner should note that claim 17 encompasses the same intended uses of the composition as recited in claim 13. Accordingly, no subject matter has been dedicated to the public as a result of the cancellation of claims 13 and 14.

(g) Claims 11-20 are said to be vague and indefinite in that the claims provide for the use of the claimed compounds, but the claim does not set forth any steps involved in determining which are the disorders capable of being treated by modulating the activity of acetylcholinesterase. The Examiner alleges that determining whether a given disease responds or does not respond to such an inhibitor will involve undue experimentation. However, such comments and concerns are completely irrelevant to composition claims 11-15 since these claims are not directed to method of use claims. There is no requirement in the statute (e.g. 35 USC 112) that a composition recite steps or whether various given diseases responds to it. Further, this rejection is moot with respect to claims 18-20 since these claims have been cancelled. These claims have been cancelled because they are

non-statutory type claims under U.S. practice. The intended uses are encompassed by method claims 16 and 17, which clearly recite the active step of "administering." Thus, the Examiner's comments are not understood and are entirely without basis. Clarification or preferably withdrawal of this rejection is requested.

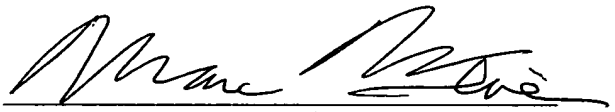
Rejection of Claims 18-20 Under 35 U.S.C. 101

Claims 18-20 have been cancelled since they are non-statutory claims under U.S. practice.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By: 

Marc S. Weiner, #32,181
P.O. Box 747
Falls Church, VA 22040-0747
(703) 205-8000

MSW/sh
0425-0877P